HFI-35 (Purged)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 24 2000

WARNING LETTER

Ref:OC:I1-1856

via FEDERAL EXPRESS

Dr. Sunny Sun
Vice President
Casix in USA
21822 Lassen St. #G
Chatsworth, California 91311

Dear Dr. Sun:

This letter is written to advise you of items of noncompliance with the Federal performance standard for laser products, 21 CFR 1040.10 and 1040.11, encountered during an inspection of laser products which your firm manufacturers, imports and/or distributes in the United States (U.S.). Mr. Gary Zaharek and Ms. Suzie Kent of the FDA Los Angeles District Office conducted the inspection on March 1, 2000, at your Lassen Street facility.

This letter is also to notify you that the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA) hereby disapproves the quality control and testing program for laser products produced by or for Casix, Inc. This action is taken under the authority of the United States' Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C - Electronic Product Radiation Control.

The following items of noncompliance were noted during the inspection of representative models available for evaluation at the time of the inspection:

1. A model DPGL 1030 Serial Number (SN) 10677 (Class IIIb) lacked a remote interlock connector, an emission indicator, manufacturers identification and a date of manufacture. It was also noted that the end cap of this product was easily removable permitting invisible radiation to exit the product. Although this end cap is not intended to be removed during operation it must be permanently affixed in place or the product classified based on emission of both visible and invisible radiation and be compliant with applicable requirements.

2. 21 CFR 1040.10(f)(3) Remote interlock connector and (1040.10(f)(5)(ii) emission indicator. The models LDC-1500, LDC-2500 and LDD-600 lacked remote interlock connectors and laser radiation emission indicators as required by these sections.

3. A model DPGL 3000 series, Model 3002 SN 32626 (Class IIIa) lacked a certification label, identification of the manufacturer and date of manufacturer.

4. Two model DPIR 2000 Series, Model 2200 SN 20518 and SN 20377 (Class IIIb) lacked certification and identification labels and a date of manufacturer.

5. A model DPGL 3000F series, Model 3005 SN 31954 (Class IIIa) lacked an identification of the manufacturer and a date of manufacturer. The warning logotype affixed to the product contained incorrect wording and incorrect radiation output information.

6. A model DPGL 4000 being sold as a component or replacement part was not label in accordance with 21 CFR 1040.10(a)(2)(i) and (ii) applicable to laser products sold to manufacturers for these purposes.

7. 21 CFR 1040.10(h)(2)(i) Purchasing information. The Casix 1999 sales catalog failed to include, as required by this section, a reproduction of the warning logotype required to be affixed to the product.

Mr. Zaharek and Ms. Kent were informed that the above observations were typical for similar models of these laser products your firm has distributed nationwide.

Section 538(a) of the Act, prohibits any manufacturer from certifying or introducing into commerce laser products which do not comply with the standard. This section also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports. Failure to respond to this letter may be considered to be a violation of paragraph 538(a)(4) of the Act. The FDA is prepared to invoke regulatory actions if you fail to comply with these requirements. These actions may include an injunction and/or imposition of civil penalties as provided for in Section 539. Persons failing to correct violations and/or continued violations of the Act are subject to civil penalties of up to $1,000 per violation and up to a maximum penalty of $300,000 without further notification by the FDA. In cases where a foreign manufacturer fails to respond, penalties may be imposed upon importers.

You must respond in writing within 15 days of receipt of this letter to one of the options listed below. In your response you must also provide the number of the referenced products which have been produced and the number of such products that have left the place of manufacture. In addition, if the product distribution was confined to specific geographical areas of the United States, please specify those areas.

1. Refutation - You may submit your views and evidence to establish that the alleged failures to comply do not exist.

2. Exemption Request - You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31).

3. Purchaser Notification and Corrective Action - If you neither refute the noncompliance nor request an exemption, then you must: (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (b) submit a written corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products.

    a. Notification Letter - Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers and dealers must also be sent to the FDA. It is recommended that you submit a draft of this letter to us for review.

    b. Corrective Action Plan - Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, or 1004.4.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an acceptable CAP cannot be prepared promptly, you may be required to proceed with interim notification to affected persons as required by 21 CFR 1003.11(c) and 1003.21. Therefore, you are encouraged to immediately begin your preparation of an accurate user location list.

The following failures to comply with the regulations regarding reports and record keeping were observed:

1. 21 CFR 1002.10 and 1002.11 Product reports: Your firm has failed to submit product reports or supplemental reports as required by this section for the following model laser products: DPGL-1000 Series, DPIR-2000 Series, DPGL-2000 Series, DDGL-3000 Series, DPLL-3000 Series, and DPIR-1000 Series. In a letter dated October 8, 1998, your firm stated that a product report for the Polaris model green laser pointer was being submitted. In our letter dated April 12, 1999, we requested that you resubmit that report because we were unable to locate the report in our files. To date we have not received any response to our letter.

2. 21 CFR 1040.10(3)(i): Your firm has failed to register and list those laser products that are not certified and are distributed as components or replacement parts.

3. 21 CFR 1002.11: Annual reports. Your firm has failed to submit annual reports as required by this section.

Based on the findings listed above, the CDRH declares that Casix, Inc., has failed to conduct a testing program, which ensures compliance with the applicable requirements of the laser performance standard. In addition your firm has failed to submit required reports and to respond to correspondence as requested. The CDRH therefore, under authority of 21 CFR 1010.2(c), disapproves the testing and quality control program for laser products produced by or for Casix, Inc.

This disapproval means that your firm is prohibited by Sections 534(h) and 538 of the Act from:

1. certifying the electronic products manufactured under the disapproved testing program,

2. introducing or importing products into the U.S. commerce which bear false and misleading certification, that is, products certified under the testing program which has been disapproved, and

3. introducing or importing into the U.S. commerce any product, which does not have the certification label permanently, affixed to the product, as required by 21 CFR 1010.2.

Under Section 536(a) of the Act, the CDRH is required to refuse entry or importation into the U. S. commerce of any electronic product if it appears that the product fails to comply with the applicable standards, or the manufacturer's testing program has been disapproved. In this regard, we have added your firm to FDA Import Alert 95-04. This alert may be viewed on Internet web site: http://www.fda.gov/ora/fiars/ora_import_ia9504.html.

To resolve this matter, you must submit all the information required under 21 CFR 1002.10 such that the CDRH can determine that Casix, Inc., is in compliance with the Act, that the subject products comply with the performance standard, and that the testing program is in accord with good manufacturing practices.

The CDRH will advise you whether your submittal is satisfactory.

Your response should be sent to: Director, Division of Enforcement III (HFZ-340), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. You are also requested to send a copy of your response to: Director, Compliance Branch, Los Angeles District Office, Food and Drug Administration, 19900 Mac Arthur Blvd., Suite 300, Irvine, California 92612. If you have further questions on these requirements, please contact Frank W. Mackison of the Electronic Products Branch at (301) 594-4654.

Sincerely yours,

Lilian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

CC: Mr. Hong Rui Wang, President
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